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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,763	05/12/2005	Heinz Peter Vollmers	50308/003001	8912

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EXAMINER	
HALVORSON, MARK	
ART UNIT	**PAPER NUMBER**
1642	

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07/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,763	VOLLMERS ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7-16 and 54-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7-16 and 54-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4 7-16 and 54-65 are pending and under examination.

Objections to Specification withdrawn

The objections to the specification are withdrawn in view of Applicant's amendments to the Specification.

Objections to Claims withdrawn

The objection of claims 2 and 4 is withdrawn in view of the amendments to claims 2 and 4.

35 USC § 112 1st paragraph rejection maintained

Claims 1, 2, 4, 7-11, 14 and 15 remain rejected and amended clams 12 and 13 along with new claims 54-65 are rejected for failing to comply with the enablement requirement.

The claims as amended teach isolated antibodies comprising the amino acid sequence with 85%, 90% or 95% identity to SEQ ID NO:1 and/or the amino acid sequence with 85%, 90% or 95% identity to SEQ ID NO:3. In addition, claim 63 teaches a purified antibody wherein the antibody comprises SEQ ID NO:1 and SEQ ID NO:3 with a conservative substitution in either SEQ ID NO:1 or SEQ ID NO:3.

As previously stated in the January 3, 2007 Office Action, it is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al. (Proc Natl Acad Sci USA 1982 Vol 79 page 1979).

Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that antibodies as defined by the claims which may contain less than the full complement of heavy and light chain variable regions, have the required binding function of inducing apoptosis. The specification provides no direction or guidance regarding how to produce antibodies as broadly defined by the claims. Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the written disclosure alone.

Furthermore, there is no functional language associated with the functional fragments of claims 9, 10 and 11. Thus, the functional fragments are not enabled because the claims do not indicate that the functional fragments bind to the same antigen as the purified antibody.

In addition, claims 64 and 65 recite proteins comprising a single heavy chain variable region or a single light chain variable region. It would be understood that a single heavy chain variable region or a single light chain variable region would not bind antigen. Amending the claim to read on a purified antibody would obviate this rejection.

35 USC § 102(e) rejections withdrawn

The rejection of claims 1, 2, 4 and 13 under 35 USC 102(e) as being anticipat4ed by Zhou et al is withdrawn in view of the amendments to claim 1.

NEW REJECTIONS: Based on submission of IDS

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4 7-16 and 54-65 are rejected under 35 U.S.C. 102(a) as being anticipated by Brändlein et al (IDS 2002) as evidenced by the specification.

The claims are drawn to a purified antibody or functional fragment that specifically binds to at least one of HT-29 (ATCC Accession No. HTB-38; DSMZ Accession No. ACC 299), CACO-2 (ATCC Accession No. HBT-37; DSMZ Accession No. ACC 169), COLO-320 (DSMZ Accession No. ACC 144), COLO-206F (DSMZ Accession No. ACC 21), or COLO-678 (DSMZ Accession No. 194) and comprises SEQ ID NO:1 or SEQ ID NO:3.

Brandlein, et al. teach a monoclonal antibody CM-1 isolated from the spleen of a patient with a stage T2N0, grade G2 tumor of colon adenocarcinoma (see table 1). The specification of the instant application discloses that the amino acid sequence of SEQ ID NO:1 is the heavy chain variable region of the CM-1 human monoclonal antibody and the amino acid sequence of SEQ ID NO:3 is the light chain variable region of the CM-1 human monoclonal antibody. (page 15, lines 23-28). Furthermore, the instant specification discloses the CM-1 antibody was isolated from the sleen of a patient having stage T2N0, grade G2 colon adenocarcinoma. (see Example 2).

The product of the claim CM-1 is defined in terms of a laboratory designation rather than by physical characteristics, structure or even the process by which the product is prepared. Consequently, comparison of this product with the prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Thus a lesser burden of proof is required to make out a case of anticipation for a product claimed in terms of a laboratory designation than when claimed in conventional fashion by its physical characteristics, structure or even in terms of the process by which it is made.

Therefore, it is the Examiner's position that Brandlein, et al. have produced hybridomas which secrete antibodies that are directed to the same antigen that the claimed antibodies bind. One of ordinary skill in the art would reasonably conclude that Brandlein's antibody also possesses the same structural and functional properties as those of the antibodies claimed and, therefore, it appears that Brandlein, et al. have produced hybridomas that secrete antibodies that are identical to the claimed antibody. Since the Patent and Trademark Office does not have the facilities for examining and

comparing the claimed hybridoma and antibody with the hybridoma and antibody of Brandlein, et al., the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed hybridoma and antibody and the hybridoma and antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Since the origins of the instantly disclosed antibody and the Brandlein, et al. antibody are the same, the sequence of the Brandlein, et al. antibody would be the same as the instant application, absent evidence to the contrary that the CM-1 antibody of Brandlein, et al. and the antibody of the instant application are in fact different antibodies. As such, all the limitations of the claims have been met.

Submitting a translation of the foreign priority document Germany 102 10 427.1 would obviate this rejection.

Summary

Claims 1, 2, 4 7-16 and 54-65 stand rejected

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 16, 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/Misook Yu/
Primary Examiner, Art Unit 1642